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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|-----------------------|------------------|
| 10/772,374 | 02/06/2004 | Benjamin Gaston | 28195-503 CON | 6783 |
| 30623 | 7590 | 11/17/2006 | EXAMINER | |
| MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C. ONE FINANCIAL CENTER BOSTON, MA 02111 | | | HENLEY III, RAYMOND J | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1614 | |

DATE MAILED: 11/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/772,374

Applicant(s)

GASTON ET AL.

Examiner

Raymond J. Henley III

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

CLAIMS 1 AND 9 ARE PRESENTED FOR EXAMINATION

Applicants' response and the declaration of Jonathan S. Stamler under 37 C.F.R. § 1.132 filed October 26, 2006 have been received and entered into the contents of the application.

Claim Rejection - 35 USC § 103

Claims 1 and 9 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Garvey et al., (U.S. Patent No. 6,331,543) in view of Stamler (U.S. Patent No. 6,314,956; "Stamler '956") and Stamler et al. (U.S. Patent No. 5,380,758; newly cited by the Examiner "Stamler '758"), each of record, for the reasons of record as set forth in the previous Office action dated July 13, 2006 at pages 2-9, which reasons are here incorporated by reference.

Applicants' remarks the statements of the declarant have been carefully considered, but fail to persuade the examiner of error.

In traversing the present rejection, applicants have offered that none of the references teach or suggest the administration of the claimed actives in the manner presently claimed, i.e., to the nasal mucosa and osteomeatal complex. Further, applicants have remarks, and the declarant has stated, that there are several advantages attendant to such manner of administration over other systemic delivery methods, e.g., non-invasiveness, efficient absorption via highly-vascularized mucosa, rapid onset of action, improved compliance, avoidance of any degradation and/or unwanted metabolism of the drug, which can change the drug's molecular structure and potential for direct delivery to the brain via the tight junctions present in the nasal mucosa and osteomeatal complex, (see applicants' remarks at pages 3-4 and the declaration at pages 2-3).

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In the examiner's opinion, this fails to overcome the present presumption of obviousness because of the prior art teachings of "inhalation spray", (Garvey et al. at col. 58, line 20 and "*intranasal* delivery", (Stamler '758 at col. 4, line 53, emphasis added) as means for administration. While Garvey et al. do not mention nasal delivery, the examiner knows of only two anatomical sites where inhalation may take place, i.e., the nose and mouth. Thus, the teaching of "inhalation" in Garvey et al. represents a genus which has a sufficiently small genus so as to have placed each species thereof, i.e., through the mouth and through the nose, into the possession of the public. No further comment is deemed necessary as to the teaching Stamler '758 which is directly on point in teaching "intranasal" delivery. Also, as to Stamler '956, while the patentees highlight that ethyl nitrite is to be delivered to the lungs, such is not seen to be distinct from that which applicants are here doing because the patentees teach administration of ethyl nitrite in the form of a gas and by means of a "face mask", (see col. 4, lines 17-28 and 38). Clearly, given a face mask would be placed over both the nose and the mouth, it is not seen how the gas could not be inhaled through the nose and passively absorbed through the nasal mucosa and osteomeatal complex.

Also, while applicant and declarant have pointed to several advantages to administration to the nasal mucosa and osteomeatal complex, it has not been established that such would not have been readily expected by one of ordinary skill in the art or else would represent results that would have been greater than expected or otherwise unexpected.

Accordingly, for the above reasons, the examiner is maintaining the propriety of the present rejection.

None of the claims are currently in condition for allowance.

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THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

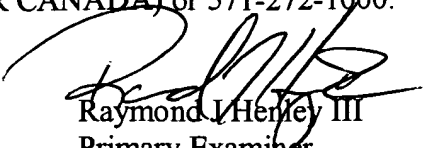
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

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like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Raymond J. Herley III
Primary Examiner
Art Unit 1614

November 9, 2006